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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,742	04/18/2001	Robert H. Marchessault	1770-251US KPM:ER	9738

20988 7590 06/15/2004
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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,742	MARCHESSAULT ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6,7 and 11-16 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10, 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on March 15, 2004 has been acknowledged and entered.

Claims 1-19 are pending.

Withdrawn Rejection(s)

Rejection under 35 USC 112, 2nd paragraph is withdrawn herein.

Rejection under 35 USC 102 by Seiver and Veiga and Gunther are withdrawn herein.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-10, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunther et al. (US 6,123,920).

Gunther teaches composite nanoparticles, comprising superparamagnetic iron oxide core provided with a coating of comprising an oxidatively cleaved starch coating.

Natural starches are a combination of linear amylose and the branched amylopectin polysaccharides. While amylose content is acceptable it is preferred not so high as to cause retrogradation. The hydrophilic branched polymer is preferable because it provides dispersed precipitation seeding sites within the aqueous medium

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allowing uniform small precipitate particles to form. (see col. 3, line 39-col. 5, line 21).

These particles can be conjugated to biotargeting agents and used for imaging the targeted tissues or organs. (see col. 2, lines 26-29).

However, Gunther fails to teach that the gelatinized starch granules comprising a framework of amylopectin from which amylose chains have been expelled and the matrix is permeable and has accessible interior surfaces defining a cage for physical or chemical entrapment of antigens or antibodies.

Gunther teaches that the use of non-branched hydrophilic polymers is not effective. (see col. 4, lines 35-40). Since Natural starches have linear amylose and branched amylopectin, it would have been obvious to one of ordinary skills in the art to cleave the linear amylose and just use the branched amylopectin as a more effective matrix. Although amylose is acceptable but not so high. Thus, for a more effective result and to avoid high contents of amylose, it would have been obvious to one of ordinary skills in the art to expel the amylose chains. Furthermore, high content of amylose causes retrogradation. Regarding the cage for physical/chemical entrapment of antigens or antibodies, since Gunther teaches that the magnetic particles are within the hydrogel matrix and the biotargeting agents need to be conjugated with the magnetic particles, one of ordinary skills in the art would find it obvious that the matrix must be permeable and has accessible interior surfaces for the biotargeting agents to reach the magnetic particles within said matrix.

Response to Arguments

Applicant's arguments filed March 15, 2004 have been fully considered but they are not persuasive.

Applicants submit that the end product of Gunther is a composite nanoparticle having a magnetic core provided with a coating of an oxidatively cleaved starch with an additional polymer coating such as functionalized polyalkylene oxide instead of magnetic particle dispersed within the matrix which may be derived from starch as in the present invention. Applicants also argue that the nanoparticles of Gunther are employed in magnetic resonance imaging and the purpose of the starch and polymer coatings is to stabilize the particles and prolong the blood resonance time. Furthermore, the matrix of the composition is permeable and has assessable interior surface defining a cage for physical or chemical entrapment of an immuno-reactant or diagnostic agent. Such structure is not part of the Gunther reference. Applicants also argue that the analysis of Gunther appears to be based on hindsight after the reading the specification of the present application. Nowhere does Gunther teaches a cage structure for physical/chemical entrapment of antigens, antibodies, etc. In Gunther the "gel" exists as part of the manufacturing process of the magnetic particles.

First of all, in response to Applicants' argument about the utility of the composition in Gunther, the utility of the composition is not given any patentable weight. Thus, as long as the composition of Gunther comprises all the components as those of the present invention, then Gunther meets the requirement of the claimed composition. As applicants pointed out, the "gel" only exists as part of the manufacturing process of the composite in Gunther or as an intermediate product. As long as such

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intermediate product meets the requirement of the claimed composition, then the reference is relevant as prior art. The ferrous or ferric salts (equates the particulate magnetic material of the claimed invention) and a base are combined in heated aqueous starch solution. The solution is allowed to cool so that it sets as a gel. Thus, this intermediate product has a gel matrix with particulate magnetic material dispersed therein. Regarding the property that the matrix being permeable and having assessable interior surfaces defining a cage, since the matrix in Gunther is made of the same material (starch) as that of the invention, such matrix in Gunther inherently possess the property of being permeable and having assessable surfaces defining a cage.

Allowable Subject Matter

Claims 6, 7 and 11-16 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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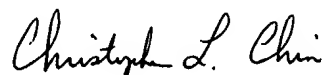
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
December 12, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641